# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Frank A. Skraly and Martha Sholl

Serial No.: 09/909,574 Art Unit: 1652

Filed: July 20, 2001 Examiner: Yong D. Pak

For: *PRODUCTION OF POLYHYDROXYALKANOATES FROM POLYOLS*

#10
M.G.J
10/28/02

Assistant Commissioner for Patents
Washington, D.C. 20231

## RESPONSE TO RESTRICTION REQUIREMENT

Sir:

Responsive to the Office Action mailed on September 23, 2002, please consider the following remarks. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge the fee to Deposit Account No. 50-1868.

The Restriction Requirement

In the Office Action mailed on September 23, 2002, the 21 claims were divided into four groups.

Group I, claims 1-10, drawn to a method of producing polyhydroxyalkanoates by providing various diols to be converted into hydroxyalkanoates. (Class 435, subclass 146)

Group II, claims 11-19, drawn to a composition comprising a polyhydroxyalkanoate copolymer with various comonomers. (Class 560, subclass 1)

Group III, claim 20, drawn to a method of improving a biological system for making polyhydroxyalkanoates. (Class 435, subclass 146)

Group IV, claim 21 drawn to a DNA fragment encoding a diol oxidoreductase and an aldehyde dehydrogenase producing various hydroxyalkanoates. (Class 536, subclass 23.2)

In response, the Applicants elect Group I, claims 1-10, with traverse.

The Restriction Requirement is Incomplete

It is expressly stated in the MPEP that the "particular reasons relied on by the examiner for holding that the inventions as claimed are either independent or distinct should be concisely stated. A mere statement or conclusion is inadequate. The reasons upon which the conclusion is based should be given." (MPEP 816).

In the Office Action mailed September 23, 2002, the Examiner fails to include reasons why the restricted groups are distinct. As such, the examiner does not meet his burden in establishing grounds for a Restriction Requirement.

Further, the Applicants assert that these claims are related to one inventive concept. Groups I and II are not distinct because they are related as method of making and product made and do not satisfy the test of distinctness. The conditions under which a proper restriction requirement can be made are where: (A) the process as claimed is not an obvious process of making the product and the process as claimed can be used to make another and different products; or (B) the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). The compositions of PHA monomers in Group II possess characteristics

that are specifically made by the method of Group I. Conversely, the method of Group I will always yield the PHAs described in Group II.

Group III is directed to a method for detecting mutant bacteria with enhanced PHA synthesis from diols. The method for Group III incorporates all the elements of Group I which would otherwise not make these two groups patentably distinct. The method of Group I is necessary to practice the method of Group III. Similarly, the method of Group III will yield PHA monomers in the same way as the method of Group I.

Group IV is related to Group I as process and apparatus for its practice (MPEP 806.05(e). To properly be restricted, the Examiner must show (A) that the process *as claimed* can be practiced by another materially different apparatus or by hand; or (B) that the apparatus *as claimed* can be used to practice another and materially different process. The method of Group I can not be practiced without the DNA fragments to encode the required enzymes for diol processing. The DNA fragments in Group IV are used to encode the enzymes function to process the diol substrate in the formation of PHAs. The specific monomers are formed as a result of using an appropriate diol precursor as the carbon source for the reaction.

<u>The Election of Species Requirement is Incomplete</u>

The Examiner also requires that an election of species be made between the following species: genus of diols, genus of comonomers, and DNA fragments encoding a genus of hydroxyalkanoates. It is impossible to respond to this requirement. The specification states that supplying a particular diol substrate as the sole carbon source will yield a specific PHA (page 4,

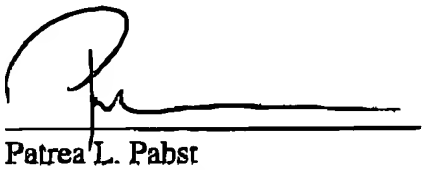
lines 3-8; page 9, line 17-18). For example, use of 1,4-butanediol will be used to synthesize 4-hydroxybutyrate. The monomer is dependent on the choice of diol used as a carbon source.

Further, the DNA fragments do not encode a genus of hydroxyalkanoates. The DNA fragments encode **two enzymes**, diol oxidoreductase, and an aldehyde dehydrogenase, which are necessary for PHA synthesis. These two enzymes can produce various hydroxyalkanoate monomers depending on which substrate is supplied as a carbon source. It is impossible to elect a species in this genus, as **there is no genus.**

Applicants elect 1,4-butanediol which will be used to synthesize 4-hydroxybutyrate.

Allowance of claims 1-21 is respectfully solicited.

Respectfully submitted,



Patrea L. Pabst
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Date: October 23, 2002
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U.S.S.N. 09/909,574
Filed: July 20, 2001
**RESPONSE TO RESTRICTION REQUIREMENT**

**Certificate of Facsimile Transmission**

I hereby certify that this paper, along with any paper referred to as being attached or enclosed, is being facsimile transmitted to the Assistant Commissioner for Patents, Washington, D.C. on this date.

Jean Hicks

Date: October 23, 2002

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## MESSAGE

Applicant: Frank A. Skraly and Martha Sholl

Serial No.: 09/909,574 Art Unit: 1652

Filed: July 20, 2001 Examiner: Yong D. Pak

For: *PRODUCTION OF POLYHYDROXYALKANOATES FROM POLYOLS*

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# TRANSMITTAL FORM

*(to be used for all correspondence after initial filing)*

Total Number of Pages in This Submission

| | |
|---|---|
| Application Number | 09/909,574 |
| Filing Date | July 20, 2001 |
| First Named Inventor | Frank A. Skraly |
| Group Art Unit | 1652 |
| Examiner Name | Yong D. Pak |
| Attorney Docket Number | MBX 039 |

## ENCLOSURES *(check all that apply)*

- [x] Fee Transmittal Form
  - [ ] Fee Attached
- [x] Amendment / Reply
  - [ ] After Final
  - [ ] Affidavits/declaration(s)
- [ ] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Response to Missing Parts/ Incomplete Application
  - [ ] Response to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Assignment Papers *(for an Application)*
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition
- [ ] Petition to Convert to a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s) _____
- [ ] After Allowance Communication to Group
- [ ] Appeal Communication to Board of Appeals and Interferences
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- [ ] Proprietary Information
- [ ] Status Letter
- [x] Other Enclosure(s) *(please identify below)*:

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Remarks

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

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| Firm or Individual name | Patrea L. Pabst, Reg. No. 31,284 Holland & Knight LLP<br>Suite 2000, One Atlantic Center; 1201 West Peachtree Street, N.E.; Atlanta, GA 30309-3400 |
| Signature | |
| Date | October 23, 2002 |

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# FEE TRANSMITTAL for FY 2002

*Patent fees are subject to annual revision.*

☒ Applicant claims small entity status. See 37 CFR 1.27

**TOTAL AMOUNT OF PAYMENT** ($) -0-

| Complete if Known | |
|---|---|
| Application Number | 09/909,574 |
| Filing Date | July 20, 2001 |
| First Named Inventor | Frank A. Skraly |
| Examiner Name | Yong D. Pak |
| Group Art Unit | 1652 |
| Attorney Docket No. | MBX 039 |

## METHOD OF PAYMENT *(check all that apply)*

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Deposit Account Name: Holland & Knight LLP

The Commissioner is authorized to: *(check all that apply)*

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## FEE CALCULATION

### 1. BASIC FILING FEE

| Large Entity Fee Code | Large Entity Fee ($) | Small Entity Fee Code | Small Entity Fee ($) | Fee Description | Fee Paid |
|---|---|---|---|---|---|
| 101 | 740 | 201 | 370 | Utility filing fee | |
| 106 | 330 | 206 | 165 | Design filing fee | |
| 107 | 510 | 207 | 255 | Plant filing fee | |
| 108 | 740 | 208 | 370 | Reissue filing fee | |
| 114 | 160 | 214 | 80 | Provisional filing fee | |

SUBTOTAL (1) ($)

### 2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

| | | Extra Claims | | Fee from below | Fee Paid |
|---|---|---|---|---|---|
| Total Claims | 21 - 21 | 0 | X | 0 | = 0 |
| Independent Claims | 13 - 13 | 0 | X | 0 | = 0 |
| Multiple Dependent | | | | 0 | = 0 |

| Large Entity Fee Code | Large Entity Fee ($) | Small Entity Fee Code | Small Entity Fee ($) | Fee Description |
|---|---|---|---|---|
| 103 | 18 | 203 | 9 | Claims in excess of 20 |
| 102 | 84 | 202 | 42 | Independent claims in excess of 3 |
| 104 | 280 | 204 | 140 | Multiple dependent claim, if not paid |
| 109 | 84 | 209 | 42 | ** Reissue independent claims over original patent |
| 110 | 18 | 210 | 9 | ** Reissue claims in excess of 20 and over original patent |

SUBTOTAL (2) ($) -0-

**or number previously paid, if greater; For Reissues, see above

## FEE CALCULATION (continued)

### 3. ADDITIONAL FEES

| Large Entity Fee Code | Large Entity Fee ($) | Small Entity Fee Code | Small Entity Fee ($) | Fee Description | Fee Paid |
|---|---|---|---|---|---|
| 105 | 130 | 205 | 65 | Surcharge - late filing fee or oath | |
| 127 | 60 | 227 | 25 | Surcharge - late provisional filing fee or cover sheet | |
| 139 | 130 | 139 | 130 | Non-English specification | |
| 147 | 2,520 | 147 | 2,520 | For filing a request for *ex parte* reexamination | |
| 112 | 920* | 112 | 920* | Requesting publication of SIR prior to Examiner action | |
| 113 | 1,840* | 113 | 1,840* | Requesting publication of SIR after Examiner action | |
| 115 | 110 | 215 | 55 | Extension for reply within first month | |
| 116 | 400 | 216 | 200 | Extension for reply within second month | |
| 117 | 920 | 217 | 460 | Extension for reply within third month | |
| 118 | 1,440 | 218 | 720 | Extension for reply within fourth month | |
| 128 | 1,960 | 228 | 980 | Extension for reply within fifth month | |
| 119 | 320 | 219 | 160 | Notice of Appeal | |
| 120 | 320 | 220 | 160 | Filing a brief in support of an appeal | |
| 121 | 280 | 221 | 140 | Request for oral hearing | |
| 138 | 1,510 | 138 | 1,510 | Petition to institute a public use proceeding | |
| 140 | 110 | 240 | 55 | Petition to revive - unavoidable | |
| 141 | 1,280 | 241 | 640 | Petition to revive - unintentional | |
| 142 | 1,280 | 242 | 640 | Utility issue fee (or reissue) | |
| 143 | 460 | 243 | 230 | Design issue fee | |
| 144 | 620 | 244 | 310 | Plant issue fee | |
| 122 | 130 | 122 | 130 | Petitions to the Commissioner | |
| 123 | 50 | 123 | 50 | Processing fee under 37 CFR 1.17(q) | |
| 126 | 180 | 126 | 180 | Submission of Information Disclosure Stmt | |
| 581 | 40 | 581 | 40 | Recording each patent assignment per property (times number of properties) | |
| 146 | 740 | 246 | 370 | Filing a submission after final rejection (37 CFR § 1.129(a)) | |
| 149 | 740 | 249 | 370 | For each additional invention to be examined (37 CFR § 1.129(b)) | |
| 179 | 740 | 279 | 370 | Request for Continued Examination (RCE) | |
| 169 | 900 | 169 | 900 | Request for expedited examination of a design application | |

Other fee (specify) _____

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## SUBMITTED BY

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|---|---|---|---|---|---|
| Name (Print/Type) | Patrea L. Pabst | Registration No. (Attorney/Agent) | 31,284 | Telephone | (404) 817-8473 |
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